

***Remarks***

**Newly added claims**

The Applicant has added three claims (claims 66, 67, and 68), dependent upon claims 48, 52, and 56 respectively. The Examiner has stated that claims 47, 52, and 56 are not directed to functions and method steps relating to the detection of non-physiologic (asymmetric) noise separate from symmetric noise. Accordingly, new claims have been added which specifically state this limitation. As claim 47 is now canceled, and its limitations incorporated into newly amended claim 48, newly added claim 66 is dependent upon claim 48 and not claim 47.

During the communication of 25 January 2005, Applicant inadvertently omitted claim 46 without reason for its deletion. Furthermore, the original text of claim 46 was entered as claim 45, and the original text of claim 45 was missing entirely. Examiner did not note the error nor the missing claim, and it was not until the current office action response that the error was identified by Applicant. Claim amendments correcting the error are hereby submitted, and include (a) renumbering current claim 45 back to its original number of claim 46, and (b) re-entering claim 45 as originally written. Should an Examiner amendment still be needed to restore the correct status and placement of these claims, Applicant will authorize it.

**Claim Rejections – Double Patenting**

The Examiner's most recent argument for rejection under the judicially created doctrine of obviousness-type double patenting is incomplete, however, a brief conversation with the Examiner revealed that the claims for which this rejection remains includes claims 29-34, 37, 47, 52, 56, 59, and 64. See Office Action of 28 November 2005 page 3-4 stating “[c]laims 28-35, 37, 42, 47, 52, 53, 56, and 59 are overall broader than the corresponding claims 1, 3, 6, 7, 8, 33, 34-38, 44, and 45 and thus it would have been obvious that anything that infringed on the narrower” (sic). The above-referenced brief

conversation with the Examiner revealed that the Examiner intended to copy and paste language from a previous office action but for some reason only a partial amount of the text was copied. Regardless, for the remaining claims of those originally named in the Double Patenting rejection (specifically, claims 29-34, 37, 47, 52, 56, 59) and claim 64, Applicant hereby submits with this response a Terminal Disclaimer in compliance with 37 C.F.R. §1.321(c).

Accordingly, the Examiner's rejection of the foregoing claims on the grounds of obviousness-type double patenting have been overcome, and the rejection should properly be withdrawn.

**Claim Rejections under 35 U.S.C. §102(b)**

With regard to claims 29-31, 33, 40, 41, 43, 45, 47, 51, 52, 62, and 64 the Examiner has discovered a new reference to Neely et al. (U.S. Pat. No. 5,697,379) which the Examiner has used as a basis for an anticipation rejection. In light of this newly discovered art, Applicant hereby adds further limitations to claims 29, 31, 33, 41, 45, 52, and 64, cancels claims 30, 32, 34, 43, and 47, and argues for allowance of claims 40, 51 and 62.

Claims 30, 32, 34, 43, and 47 have been cancelled, thereby obviating the anticipation rejection of those claims. In light of these cancellations, amendments have necessarily been made to claims 44 and 48, which if not amended would have been dependent upon a canceled claim. Specifically, claims 44 and 48 are hereby written in independent form, incorporating all limitations of the now-cancelled claims upon which they formerly relied. Claim 44 is rewritten in independent form, incorporating all limitations of now canceled claim 43. Claim 48 is rewritten in independent form, incorporating all limitations of now canceled claim 47.

The Examiner rejected claim 40 for anticipation under the assumption that claims 33, 40, 47, and 52 shared common features. While some features are shared among these four claims, a limitation exclusive to claim 40 eliminates anticipation based upon the disclosure from Neely. In an argument for the rejection of claim 40, the Examiner notes that Neely discloses a “[m]eans for repeatedly delivering an auditory stimulus . . . [m]eans for sampling an EEG response to said stimulus, said EEG response including a noise component . . . [m]eans for determining the polarity bias of said noise component . . . and [m]eans for detecting the degree of polarity bias in said noise component and for determining when said bias is excessive relative to a threshold.” See 28 November 2005 Office Action page 8. Based on the above disclosures, claim 40 the Examiner rejected without taking into account that claim 40 further includes a “means for determining when adverse evaluation conditions are present, based upon both said noise magnitude and said noise polarity bias.” See claim 40.

The Applicant posits that determining when a polarity bias is excessive relative to a threshold is not the same as determining when adverse evaluation conditions are present based upon *both* noise magnitude and noise polarity bias. First, none of the citations provided for by the Examiner disclose detecting the noise magnitude. Second, there is nothing from Neely to suggest that said nondisclosed noise magnitude could be used in connection with the noise polarity bias to determine whether adverse evaluation conditions exist. Courts have determined that the initial burden of presenting a *prima facie case of anticipation* lies with the Examiner (*In re Warner*, 154 USPQ 173, 178 (CCPA 1967)). Here, the scope of the claim is narrow enough that Neely cannot be used as the single art reference disclosing each of the claims elements. For this reason, a 102(b) rejection cannot stand. Applicant respectfully requests that the Examiner review the scope of claim 40 in light of the above arguments.

Claim 51, now dependent on a narrower claim 48, should now be allowed.

With regard to claim 62, the Examiner has stated that all elements are disclosed in Neely, when in fact at least one element is clearly not. Specifically, the Examiner has stated that Neely discloses, among other things, a method “wherein the ambient acoustic noise is sampled during the time the auditory stimulus is delivered.” 28 November 2005 Office Action page 9. To support this, the Examiner cites Neely at column 5 line 65 – column 6 line 30. The Applicant has reviewed these lines from Neely and does not agree that Neely discloses sampling the ambient acoustic noise. At column 6, lines 12-14, Neely discloses that the “amplifiers are Opto-isolated to protect the test subject from any stray voltages” but this would seem to suggest that ambient acoustic noise is actually *prevented* from being sampled. Regardless, nothing within these lines from Neely would suggest that as a step to the process ambient acoustic noise is sampled. As to claim 62, the Examiner has not met the *prima facie case of anticipation* and Applicant thus respectfully requests the Examiner reconsider the allowability of this claim.

In light of the amendments and remarks pertaining to claims 29, 31, 33, 40-41, 45, 51-52, and 64, Applicant respectfully requests reconsideration of the anticipation rejection based on Neely et al.

**Claim Rejections under 35 U.S.C. §103 (a)**

The Examiner has rejected claims 32, 34, 36, 60-61, and 63 under 35 U.S.C. §103(a) as obvious over Neely in combination with various prior art sources. In reliance upon the Examiner’s findings and arguments, Applicant hereby cancels claim 63 and amends claims 36, 60 and 61.

First, Applicant notes that claims 32 and 34 were rejected by the Examiner on Office Action page 10 as unpatentable over Neely et al. “in view of Thornton (sic) et al. (US 4,275,764 (sic)).” Applicant notes from the file history that Examiner intended to reference Thornton et al., U.S. Pat. No. 4,275,744. Applicant further notes that claims 32

and 34 are now canceled, but the limitations formerly therein compose newly amended claims 31 and 33. Although Applicant disagrees that the disclosed subject matter in Thornton shows more than simply the general subject matter of the claimed invention, limitations have been added to these claims (31 and 33) to more precisely define the subject matter. It is Applicant's contention that there is low likelihood that the prior art would have suggested to one of ordinary skill in the art that these additional claim limitations would have been carried out with a reasonable likelihood of success.

The Examiner has rejected claim 36 under 35 U.S.C. §103(a) as unpatentable over Neely in view of Keefe (5,792,072). The Examiner attributed teachings to Neely involving an "earphone that implicitly detects some degree of ambient acoustic noise." In combination with this, the Examiner argues that this means for detecting ambient acoustic noise is disclosed in Keefe in the form of a microphone. The fact is, the earphone in Neely is not described to have the capability to detect ambient acoustic noise. Column 4, lines 48-49 in Neely state that the method calls for the "use of earphones to transmit the hearing stimulus to the test subject." Column 6 lines 59-60 state "the audio stimulus was transmitted to the testing subject by means of earphones 32." There is no indication that these earphones also implicitly *detect ambient* acoustic noise, and indeed, the Examiner gave no citation to Neely where this is shown.

Neely does, however, address the issue of noise, although first it pertains to noise as in data produced as an unwanted by-product of other activities, specifically neural activities. This noise is not necessarily *acoustic* noise as required by Applicant's claim 36, and as would be detected by the microphone in Keefe. Neely also discusses *residual* noise in the averaged waveform but it is unclear that this is "ambient acoustic noise." Webster's Encyclopedic Unabridged Dictionary of the English Language defines ambient as "of the surrounding area or environment: *The tape recorder picked up too many ambient noises.*" This is in accord with page 3 line 20-21 of Applicant's specification, stating "this invention allows for an improved determination of whether the ambient acoustic noise *in*

*the test site* is excessive. Furthermore, Applicant's claim, newly amended, is limited to only *acoustic* noise external to said subject, which excludes the general all encompassing definition of noise as in data produced as an unwanted by-product of other activities.

Furthermore, even if the earphone did implicitly detect some degree of ambient noise, such detection was not the focus of the procedure in Neely. The procedure in Neely was not focused on the detection of ambient acoustic noise, and even if one component implicitly detected such noise, one of ordinary skill in the art would not have likely found it obvious to combine such detection with anything. It is well settled that "the consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success." Rockwell Int'l Corp. v. United States, 47 USPQ2nd 1027, 1033 (Fed. Cir. 1998). Plainly stated, it could not have been obvious for someone to combine Neely with a microphone if they did not know the importance of ambient acoustic noise to begin with.

The Examiner has rejected claims 60 and 61 under 35 U.S.C. §103(a) as unpatentable over Neely in view of Applicant's admitted prior art. The Examiner has stated that Neely discloses detecting noise associated with an EEG response, and while this may be true, the noise would be either due to "other ongoing neural activity, muscle activity, and non-physiological, environmental sources" (Column 2, lines 5-7) or due to "residual noise in the averaged waveform," (Column 8, lines 25-30). This type of noise is dissimilar from the ambient acoustic sound required in Applicant's claims 61 and 62. To clarify this difference, claims 61 and 62 are hereby amended to more specifically claim ambient acoustic noise generated externally from the subject.

### **Claim Rejections under 35 U.S.C. §112**

The Examiner has rejected claims 33, 34, 40, 47, 52, and 56 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Of these claims, claim 34 and 47 have been canceled, thereby obviating the Examiner's rejection.

Of the remaining claims 33, 40, 52, and 56, said claims are hereby amended to comply with 35 U.S.C. §112, second paragraph. These claims, as amended, include the detection of polarity bias in either the EEG response or ABR signal. Additionally, claim 48, which newly amended now includes all limitations of its former base claim 47, is hereby amended to comply with the 35 U.S.C. §112, second paragraph in light of an anticipated rejection by the Examiner.

The Examiner rejected claim 55 under 35 U.S.C §112 second paragraph. Claim 55 recites "wherein the step of accounting for excessive amounts of said noise comprises rejecting a portion of said array of polarity sums." The specification teaches that repetitive stimuli are to be administered in blocks of  $n$  sweeps. See page 7 lines 18-19. [t]he amplitude sequence of each stimulus response is converted into a sequence of polarities, which, in turn, is summed with other response polarity sequences . . . to form the array." See page 7 line 25 – page 8 line 1. Upon consideration of these two instructions provided in Applicant's specification it becomes clear that "said array of polarity sums" claim language is sufficiently provided for in the specification. See *Bancorp Services, L.L.C. v. Hartford Life Insurance Co.*, 69 USPQ2d 1996 (Fed. Cir. 2004), stating that a phrase not described in the specification is still definite when its components were defined or described in the specification.

Regarding the second half of claim 55 ("rejecting a portion of said array of polarity sums"), the specification merely teaches that "[i]f excessive bias is indicated, the last block of sweeps may be rejected." The question thus becomes whether one of ordinary

skill in the art, when reading this claim in light of the supporting specification, would have been able to ascertain with a reasonable degree of precision and particularity the specific area set out and circumscribed by the claim. See *Ex parte Wu*, 10 USPQ 2d 2031, 2033 (BPAI 1989), *In re Moore*, 169 USPQ 236, 238 (CCPA 1971), and *In re Hammack*, 166 USPQ 204, 208 (CCPA 1970). Here, because of the level of sophistication one in the relevant art would possess, it would be a simple task to understand rejecting the last block of sweeps would equate to rejecting a portion of said array. Furthermore, one familiar in the art and in the field of computers would know that more than only the last block of sweeps could be rejected, and that due to a computer's ability to delete data, all of said array of polarity sum could very quickly and easily be deleted. Because one of ordinary skill in the art *would* have been able to ascertain the claim scope, claim 55 should hereby be allowed without substantive amendment.

Claims 38 and 60-62 were rejected under 35 U.S.C. §112, second paragraph because those claims include language regarding the sampling of ambient acoustic noise before and during the time of the auditory stimulus. Such samplings are a critical component of the invention and allow ambient noise (background noise) to be filtered out from the other test results. Most importantly, the Examiner has *already admitted on record* that the sampling of ambient acoustic noise before and during the time of auditory stimulus is taught by Applicant: *See* Office action of 28 November 2005 page 13 (stating that "the Applicant's admitted prior art teaches of wherein the ambient acoustic noise is sampled both before and during the time the auditory stimulus is delivered").

The text the Examiner highlights in the above quote states that "the ambient noise received by the microphones can be filtered before analysis, to exclude noise that is unlikely to interfere with testing by masking the auditory click stimulus." Further, upon consideration of the level of knowledge in this art field at the time of the application, it becomes clear that one of ordinary skill in the art reading this claim in light of the specification *and its references* would have easily ascertained with more than a

reasonable degree of precision and particularity that ambient acoustic noise could be sampled before, during, or after testing. *See supra Ex parte Wu at 2033, supra In re Moore at 238, and supra In re Hammack at 208.*

Finally, Applicant notes that the claim language rejected by the Examiner technically is met by a disclosure at page 11 lines 13-16, wherein Applicant describes an improved ability to detect excessive ambient acoustic noise, specifically stating that "the present invention gathers signal energy measurements in three approximately 20-millisecond windows, each placed immediately *prior* to the onset of one of the last three clicks." (Emphasis added). The Applicant then continues to describe the formula for determining excess ambient noise with a formula that describes the "pre-click windows of time" wherein said click is the auditory stimulus and said pre-click time frame is a time period before said stimulus wherein ambient noise is detected. See application page 11 line 20.

In light of all of the above, Applicant requests reconsideration of the 35 U.S.C. §112 paragraph two rejections of claims 38 and 60-62.

### **Claim Objections**

The Examiner has stated that claims 39, 44, 48-50, and 57-58 "would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Regarding claim 39, this claim is dependent upon claim 38, a claim rejected by the Examiner under 35 U.S.C. §112 second paragraph. Arguments for the allowance of claim 38 are presented above and no amendments are made to claim 39 at this time.

Regarding claim 44, this claim is currently rewritten in independent form, and now includes all limitations of its former base claim 43, which is now canceled. Applicant

notes that claim 44 is not a claim that was affected by the Examiner's 35 U.S.C §112 second paragraph rejections, nor was it dependent on such a claim. Therefore, since this claim now fully complies with the Examiner's objection (see Office Action of November 28, 2005 page 13), Applicant submits that this claim is now ready for allowance.

Regarding claim 48, this claim is currently rewritten in independent form, and now includes all limitations of its former base claim 47, which is now canceled. Furthermore, claim 48 has been amended so as to be in compliance with 35 U.S.C. §112 second paragraph. Therefore, since this claim now fully complies with Examiner's objection (see Office Action of November 28, 2005 page 13), Applicant submits that this claim is now ready for allowance.

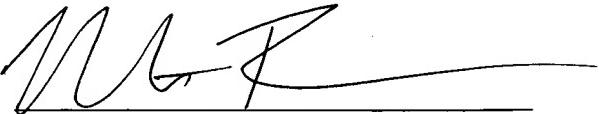
Regarding claims 49-50, these claims are dependent on claim 48, which now fully complies with all of Examiner's rejections and objections, and Applicant respectfully submits that said claims similarly be allowed.

Regarding claims 57-58, Applicant notes that the base claim on which they depend has been brought into compliance with 35 U.S.C. §112 second paragraph. However, claims 57-58 are not currently re-written into independent form because the Examiner's only other rejection to claim 56 has been overcome through a Terminal Disclaimer filed with this office action reply. Because all rejections to claim 56 have been overcome, Applicant hereby submits that claims 57-58, dependent on claim 56, are ready for allowance.

***Conclusion***

In light of the remarks and amendments detailed above, which address each rejection and objection by the Examiner, Applicant respectfully requests reconsideration and allowance of the application.

Dated: 24 March 2006

By: 

Mathew J. Temmerman, Reg. 54487

Tel: (530) 750-3661